

Exhibit “D”



Operations & Quality Systems Improvement Experts
113 Painted Trellis, Irvine, CA 92620
www.oqsie.com

February 15, 2020

Anthony Tabasso, President & CEO
KVK Tech
110 Terry Drive
Newtown, PA 18940

Re: Proposal to Support Warning Letter Response and Remediation Planning

Dear Anthony:

Thank you for the opportunity to support you and your team on this critical assignment. Below you will find our proposal to provide support.

Background

February 11, 2020

- KVK Tech received a Warning Letter from the FDA.

February 13th

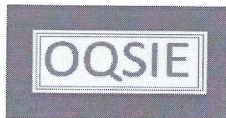
- David Rosen of Foley & Ladner introduced OQSIE to Anthony Tabasso, President & CEO for KVK Tech to potentially support remediation of the Warning Letter.
- OQSIE spoke with Anthony and a face-to-face meeting was set for February 14th.
- OQSIE delivered resumes for consultants qualified and available to support the response and remediation planning activity

February 14th

- OQSIE met with KVK at their Newtown, PA office with Steve Lynn, FDA & Industry Executive, by telephone, to discuss approach and capabilities. KVK awarded OQSIE the support role.

Deliverables

- Guide development of KVK's response to the 12Feb20 Warning Letter,
 - Presented in a coherent manner with a diligent but reasonable execution plan.
 - Laying out a story line to include activities completed for prior 483 observations covered by the Warning Letter and activities initiated during the response preparation period.
- Organize and set-up the remediation Program Management Office (PMO) including:
 - Governance committee, communication plan, and governance related activities
 - Work streams aligned with deliverables set out in the response to the Warning Letter
- Define remediation execution and resource plans
- Determine remediation budget



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OQSIE's Support Plan

Activities will be broken out into two Phases, each approximately 3 weeks long. Phase I will focus on the response to the Warning Letter, Phase II will focus on developing remediation execution and resource plans.

OQSIE's team will be composed of three senior consultants, all three are under confidentiality with OQSIE and have received all documents KVK shared. Below you will find a high-level description of the roles each will play and contributions each will make, not intended to be comprehensive:

- Steve Lynn
 - Steve's will assist in the development of the response to the Warning Letter.
 - Will provide ad hoc support through the response negotiation and remediation planning process including, as requested, support with communications with FDA and KVK Leadership.
 - Will guide remediation planning from FDA perspective / prioritization.
 - Additionally, will provide support for the 'Site #2' inspection process to mediate and mitigate any potential impact of the Warning Letter on approval of that site.
 - Steve will support his activities remotely beginning Monday, February 17, 2020
- Edgardo Rivera
 - Edgardo's role will be to support the analytical QC/QA, analytical operations and data integrity activities and commitments to the FDA.
 - Will also support remediation and resource planning.
 - Will support his activities on-site beginning Monday, February 17, 2020
- Steve Broadhead
 - Steve's role will be to organize and launch the remediation PMO, organizing the governance committee, communication plan, and related activities.
 - He will organize work streams aligned with deliverables set out in the response to the Warning Letter.
 - He will guide the development of the remediation plan.
 - He will guide the development of the resource plan and associated budget for the remediation program.
 - Steve will start on February 24th, after progress is made on the draft response.

Duration and Key Activities

The duration of this project is expected to be six weeks. The critical assumption we are making is that KVK Tech will provide the resources, information, and documentation necessary to deliver on this aggressive timeframe.

Key deliverables for OQSIE for Weeks 1 to 3

- Response to the Warning Letter
- Ensure commitments captured in the Warning Letter are appropriate, reasonable
- Ensure that timelines for commitments are realistic while being appropriate from and FDA perspective



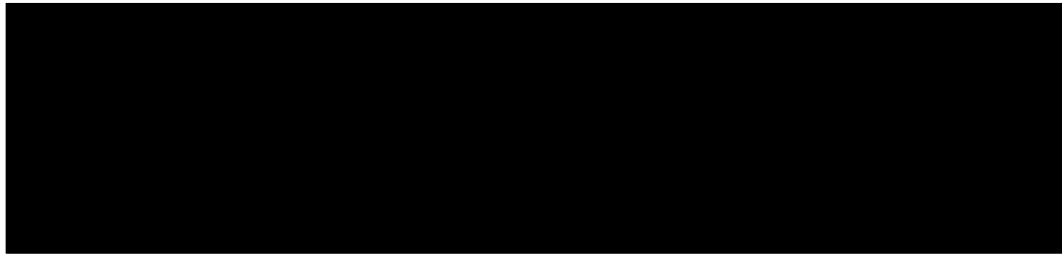
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Key deliverables for OQSIE for Weeks 4 to 6

- Detailed remediation plan to address all commitments made in the response letter
- Detailed resource plan
- Budget estimate for remediation program

Budget for this assignment

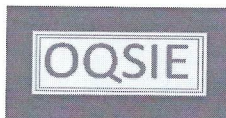
- Total budget - \$240,000
- Professional fees - \$210,000



- Expenses - estimate is \$30,000 for the duration of the project.
 - will be invoiced at cost, Edgardo and Steve B. will be onsite Monday through Friday each week, Steve Lynn as needed and agreed to.
 - Expenses will include travel to/from KVK, hotel and \$50 / day meal per diem to eliminate the need to furnish receipts for every meal.

Assumptions & Information Needed

- The consultants will work 50 hours / week unless KVK is otherwise notified. A couple of examples include:
 - Steve Broadhead will work limited hours week one as the response draft is initiated, assumed 20 hours week one.
 - Steve Lynn will work on ad hoc basis beyond week one full time, we've budget 20 hours / week for Phase I
 - NOTE: only hours worked will be billed.
- OQSIE consultants will have appropriate workspace with access to internet, people and information as needed to execute effectively.
- KVK will assign a point of contact with the OQSIE team to assist with timely organization of meetings, information gathering, key stakeholder introductions, etc.
- Once the governance structure and communication plan is agreed, both OQSIE and KVK will make their best efforts to fully participate to move the remediation execution to completion as quickly as possible.



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Please let us know if you have any questions or comments on this proposal. Please return a signed copy of this document to confirm acceptance to proceed.

Sincerely,

William Schmidt / Jaime Velez

William Schmidt / Jaime Velez
Co-Founder Partners

KVK Acceptance:



Signature

Anthony P. Tabasso, CEO

Printed Name & Title

2/17/20

Date